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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/076,260 | 02/14/2002 | Steven G. Elliott | 02-076 | 9883 |
| 20306 | 7590 | 07/20/2006 | EXAMINER | |
| MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606 | | | HAMUD, FOZIA M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1647 | |

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/076,260 | ELLIOTT ET AL. | |
| | Examiner | Art Unit | |
| | Fozia M. Hamud | 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 May 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-8, 10, 11, 43-45, 56 and 57 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-8, 10-11, 43-45, 56-57 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

Response to Amendment

1a. Receipt of Applicants' amendment and arguments filed on 26 May 2006, is acknowledged. Applicants' filing of a notice of appeal on 31 October 2005 is also acknowledged. **Status of Claims:**

1b. Claims 9, 12-42, 46-55 and 58 are canceled. Claims 1-8, 10-11, 43-45, 56-57 are pending and are under consideration.

1c. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed 05/26/2006:

(I) The rejection of claims 5-7 made under 35 U.S.C. §101 for claiming a non-statutory subject matter, is withdrawn, because the claims not recite " an isolated host cell ..."

(II) The rejection of claim 8 made under 35 U.S.C. §112, second paragraph, as being indefinite for reciting the acronym "GPCR", is withdrawn, because the claim now recites full name of the acronym.

Claim rejections-35 USC § 101:

3a. The rejection of claims 1-8, 10-11, 43-45 and 56-57, made under 35 USC § 101 is maintained for reasons of record set forth in the office actions.

Applicants argue that the specification provides a specific and substantial utility that is supported by Examples. Applicants submit that the specification demonstrates that the GPCR of the invention is highly expressed in white adipose tissues and that it is

useful in treating and/or diagnosing diseases that involve fat metabolism. Thus Applicants contend that the skilled artisan would know how to use the claimed invention.

This argument has been considered fully, but is not found persuasive. The specification does disclose that the mRNA of the instant invention is highly expressed in white adipose tissue and testis, (Example 4 and figure 5). It is also correct that the specification asserts that the claimed invention might be useful in treating and/or diagnosing diseases that involve fat metabolism, however, there is no disclosure of the role that the claimed invention plays in fat metabolism. Besides the prophetic assertion that the claimed invention may be useful in fat metabolism such as obesity and/or treatment of weight loss, (page 76, lines 15-25), there is no evidence that the claimed invention is involved in diseases that involve fat metabolism. Does the expression of the mRNA in white adipose tissue lead to obesity or anorexia nervosa? Would antagonizing the polypeptide of the instant invention be helpful to diagnose or treat obesity or anorexia? Accordingly, the claimed invention was not in a readily available form at the time the instant application was filed. The claimed invention needs further characterization to ascertain what role, if any it plays in fat metabolism, however, further characterization is part of the invention and until it had been undertaken, the claimed invention is not supported by a specific asserted utility or a well established utility.

3b. Applicants argue that the claims now recite nucleic acid encoding a polypeptide that has at least about 95% identity to the polypeptide of SEQ ID NO:2, and that such variation is within the proper scope permitted by the written description guidelines.

Applicants direct the Examiner's attention to Example 14 of the written description guidelines.

These arguments have been considered fully but are deemed unpersuasive.

Firstly, the instant specification discloses only one nucleic acid, the nucleic acid of SEQ ID NO:1 encoding the polypeptide of SEQ ID NO:2. Secondly, the recitation that the claimed nucleic acid encodes a polypeptide that has at least about 95% identity to the polypeptide of SEQ ID NO:2, is not sufficient, because the specification does not disclose an activity for the polypeptide of SEQ ID NO:2, no ligand is disclosed for said polypeptide, therefore, the skilled artisan would not be able to envision a polynucleotide encoding anything less than 100% amino acid sequence identity to SEQ ID NO:2.

Furthermore, Example 14 is drawn to a protein with a well defined function, and a claim that is limited to 95% identity to said protein and recites said function functional limitation. Therefore, the fact situation therein is substantively different from that of the instant application. While the degeneracy of the genetic code accommodates some variation in the nucleotide sequence, the extent of variation disclosed goes far beyond alternate codons for the same amino acid. A skilled artisan would expect that the variation in the polynucleotide sequence would at best code for a polypeptide that has impaired function and at worst be either nonfunctional or an entirely different product from that of the claimed invention. Therefore, it would be impossible to predict with certainty the effect of a substitution, insertion, or deletion of a series of nucleotides, or even one nucleotide, on the encoded product. In order to make an accurate assessment

of the modifications encompassed by these claims and to determine the function of the encoded protein would require undue experimentation.

Priority:

4a. Applicants contend that the subject matter defined in claims 1-8, 10-11, 43-45 and 56-57, is supported by the disclosure of the parent application.

This is not found persuasive. As set forth in sections 3a and 3b of this office action, the subject matter defined in claims 1-8, 10-11, 43-45 and 56-57 does not satisfy the requirements under 35 USC § 112, first paragraph. Therefore, the claimed invention is afforded the filing date of the current application, which is 14 February 2002.

Claim rejections-35 USC § 102:

5a. Applicants argue that the instant application is entitled to the parent priority date (14 February 2001), therefore, the cited references (WO 01/36473 published May/2001; WO 01/36471 published May/2001, WO 73029 published October/2001; WO 74904 published October/2001) cannot anticipate the claimed invention.

This is not found persuasive. The rejection of claims 1-8, 10-11, 43-45 and 56-57 under 35 U.S.C § 102(a) as being anticipated by (WO 01/36473 published May/2001; WO 01/36471 published May/2001, WO 73029 published October/2001; WO 74904 published October/2001), is maintained for reasons of record set forth in the office actions. The effective filing date of the current application is 14 February 2002, (see directly above) which is after the publication dates of the references. Therefore, this rejection is maintained.

Conclusion:

6. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


EILEEN B. O'HARA
PRIMARY EXAMINER